

USAF Dental Evaluation & Consultation Service

DECS ALERT: Lava Ultimate CAD/CAM Restorative, 3M ESPE Dental

It has been brought to the attention of the USAF Dental Evaluation and Consultation Service (DECS), validated and clarified by the manufacturer of Lava Ultimate CAD/CAM Restorative, 3M ESPE Dental, that 3M ESPE Dental is removing the crown indication from its indications for use of the Lava Ultimate blocks.

To clarify: Lava Ultimate CAD/CAM restorative material is no longer indicated for crowns.

3M ESPE Dental is removing the crown indication for 3M Lava Ultimate Restorative because crowns are debonding at a higher-than-expected rate as shown in independent studies. The material no longer meets their quality standards for this indication. The new instructions for use (IFUs) are attached and are available online at:

http://www.3m.com/3M/en_US/Dental/Products/Lava-Ultimate/

3M has stated that "Health risks associated with crown debonding have been determined to be low in severity and occurrence. There is no need to contact patients with existing Lava Ultimate restorations or to take additional action beyond normal patient care."

There will be a letter sent out this week to all users discussing the details around the correction along with an Acknowledgement/Return/Refund form. Individual clinics in the Air Force may or may not receive the letter. Details about returning the product, if desired, are available from the Customer Care Center at 1-800-634-2249. A copy of this letter and the return form are also attached.

The product continues to be indicated and can be used for inlays, onlays (with an internal retentive design element) and veneer restoratives, according to the new IFUs.







